UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S OPPOSITION TO THE UNITED STATES' MOTION TO CONSOLIDATE CASES FOR TRIAL

Dated: November 2, 2009

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PRELIMINARY STATEMENT

Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc. (collectively, "Dey") hereby submit their opposition to the United States' Motion to Consolidate Cases for Trial (Master Dkt. 6584), which seeks to consolidate the DOJ's trial against Dey, *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey, Inc., et al.,* No. 05-CV-11084-PBS (the "Dey Action") with its trial against Boehringer Ingelheim Roxane, Inc. (f/k/a Roxane Laboratories, Inc.) ("Roxane"), *U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp. et al.,* No. 07-CV-10248-PBS (the "Roxane Action").

In reading the DOJ's moving memorandum, Dkt. 6585 ("U.S. Memo"), one might think that these cases involve only one drug, ipratropium bromide, and one federal program, Medicare. The brief barely mentions Medicaid, let alone the numerous other drugs at issue. While all parties agree any trial will be lengthy and complicated, consolidation will only make matters worse for the Court and for the jury. The DOJ chose to unseal these cases separately for good reason. The evidence and proof at trial will be remarkably different for each defendant. DOJ's claim that it wishes to avoid "inconsistent results" is disingenuous: there would be absolutely nothing "inconsistent" if a jury found for Dey and not Roxane or vice versa as each case is likely to have independent, and possibly contrary, outcomes based on its own unique facts and circumstances. *See, e.g.*, *Dashnaw v. Usen*, 2006 WL 1742174, No. 1:05-cv-1592 (N.D.N.Y. June 21, 2006). What the DOJ really wants is to bolster its Medicare damages by presenting evidence in a "joint" trial for periods when it concededly cannot prove causation as to Dey or Roxane alone. The proposed consolidation of these cases would cause substantial jury confusion, a longer trial, more work for the Court, and significant prejudice to Dey and Roxane. The motion should be denied.

STATEMENT OF FACTS

The DOJ unsealed its case against Dey in 2006, and its case against Roxane in 2007. The Dey Action and the Roxane Action are separate cases with separate dockets, separate case numbers, and separate subject drug lists. Nowhere in the First Amended Complaint against Dey does the DOJ allege any conspiracy, collusion, or other "joint action" with Roxane or its sister company, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), or its parent company, Boehringer Ingelheim Corporation ("BIC"). No claim is asserted under 31 U.S.C. § 3729(a)(3), the conspiracy section of the FCA. In fact, the Roxane defendants' names do not appear anywhere in the Dey complaint. Similarly, the DOJ's Amended Complaint against Roxane is silent as to Dey. In the DOJ's recent summary judgment filings, it also fails to set forth any facts which would support a finding of conspiracy, collusion, or other "joint action" between Dey and Roxane. Rather, the DOJ alleges that Dey and Roxane were aggressive competitors. (Dkt. 6296 at ¶ 145). The DOJ's damages expert conceded he only performed "combined" damage scenarios for ipratropium bromide because Dey and Roxane had been sued and the others had not - including companies with higher AWPs for that drug. (Dkt. 6190 at ¶ 292). Clearly, the DOJ was not satisfied in seeking compensatory damages against Dey of some $375 million, but realizing that it has no legal basis to cause Dey to pay for acts caused by Roxane, the DOJ hopes to make its negligence theory of joint damages a *fait accompli* through consolidation.

Combining the two trials will simply prolong the trial beyond the point of any jury's endurance, let alone understanding. The dissimilarities far outweigh the common issues:

- At issue in the Dey Action are 26 NDCs for three generic drugs albuterol sulfate (albuterol unit dose was launched by Dey in 1992), cromolyn sodium (launched by Dey in 1994), and ipratropium bromide (launched by Dey in 1997)(the "Subject Drugs"). *See* Dkt. 6190 at ¶¶ 13, 30, 36. These drugs are all inhalation drugs used to treat respiratory diseases and are administered by nebulizer and often with home health care.

- At issue in the Roxane Action are 35 NDCs for nine drugs, Azathioprine, Diclofenac

Sodium, Furosemide, Hydromorphone, Ipratropium Bromide, Oramorph SR, Roxicodone, Roxanol and Sodium Polystyrene Sulfonate (U.S. Memo at 3), some of which are considered "branded generics."

- Azathioprine is an immunosuppressive antimetabolite which is available in tablet form used for patients who have had organ transplantation and autoimmune disease. Diclofenac Sodium is a tablet used to treat symptoms of several types of arthritis. Furosemide is a tablet diuretic used in the treatment of congestive heart failure and edema. Hydromorphone is a narcotic pain reliever available in an oral tablet. Oramorph SR is a sustained release oral tablet medicine for pain relief. Roxicodone is an oral tablet prescribed for the relief of moderate to moderately severe pain. Roxanol is a liquid preparation of morphine that is taken orally. Sodium Polystyrene Sulfonate is a tablet medication used to treat abnormally high potassium levels. None of these drugs involve nebulizers or other durable medical equipment.

- The only drug at issue in the Dey Action which overlaps with the drugs in the Roxane Action is ipratropium bromide.

- The time frames at issue in the Dey Action and the Roxane Action are different. For Dey, the DOJ's allegations run from 1992 to 2003 for Medicare, and from 1992 to date for Medicaid. For Roxane, the DOJ's allegations run from 1996 to January 1, 2004 for Medicare, and from 1996 to the present for Medicaid. The DOJ admits in its Motion to Consolidate that in the Roxane case, for all drugs other than ipratropium bromide, their claims do not begin until February 15, 1999.

- The drug by drug evidence that will need to be presented to a jury on the pricing, marketing, sales, and government reimbursement policy and knowledge regarding the 11 non-overlapping drugs will differ drastically and prolong the trial by weeks.

- Even with respect to ipratropium bromide, the DOJ, Dey, and Roxane will have to present different evidence, witness testimony, and experts to explain how Dey or Roxane priced, marketed, and sold its ipratropium products, as well as present evidence as to the individual scienter and causation of Dey and of Roxane (and its sister and parent companies if they are still in the case). This is in large part because the companies marketed their products in very different ways.

Dey: During the time at issue, Dey was a niche, specialty pharmaceutical manufacturer focused on the development, manufacturing, and marketing of prescription drugs used to treat respiratory diseases and allergies. (Dkt. 6181 at ¶ 4.) In 1992, the FDA approved Dey's albuterol unit dose ANDA, and the product launched in March of that year. (*Id*. at ¶ 16.) Dey subsequently pursued opportunities to launch other generic respiratory inhalation solutions, and launched cromolyn sodium ("cromolyn") and ipratropium bromide ("ipratropium") products in

May, 1994 and January, 1997, respectively. (*Id*. at ¶¶ 30, 33, 36.) By the late 1990s, Dey decided to switch its business model to focusing on developing, manufacturing and selling branded inhalation solutions, which are not at issue in this case. (*Id*. at ¶ 40.) Dey consistently has reported declining WACs for the Subject Drugs throughout the relevant time frame and essentially flat AWPs which it set at launch according to its understanding of the generic industry practice. (Dkt. 6190 at ¶¶ 74-80). The Subject Drugs, especially albuterol sulfate, have been the subject of numerous specific OIG reports, CMS action, as well as FULs and SMACs. (Dkt. 6190 at ¶¶ 117-135). The DOJ seeks some $160.2 million in Medicaid damages from Dey and about $215 million in Medicare damages in its Dey-alone damage scenario.

Roxane: Dey's history can be contrasted with that of Roxane. Roxane has been a manufacturer and seller of predominantly generic pharmaceuticals in the United States. Roxane was first organized in 1885 as Columbus Pharmacal, a small regional pharmaceutical manufacturer. (BIPI SOF, Dkt. 6195, at ¶ 10). During the time frame at issue, Roxane was headquartered in Columbus, Ohio. (*Id*. at ¶ 11). Currently, the Roxane product line consists of roughly 400-500 NDCs, making Roxane's drug portfolio much more diverse than Dey's. (Roxane SOF, Dkt. 6202, at ¶ 97). Unlike the Dey Subject Drugs which are all inhalation drugs, Roxane's products are almost all self-administered drugs, taken by the patient in tablet, capsule, or liquid form, including the drugs at issue in this case. (Id. at ¶ 98). Roxane's drugs also include "branded generics." Roxane's sister corporation, Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), owned Atrovent, the brand ipratropium product. (Dkt. 6195, at ¶¶ 5, 67). In June of 1996, Roxane launched the first generic ipratropium. (*Id*. at ¶ 67). Roxane stopped reporting WACs for its products in December, 1997. (Dkt. 6202, at ¶ 113). It has raised AWPs for some of its Subject Drugs from time to time. (Fauci Ex. 3, Dkt. 6207). Some of the Roxane drugs are

subject to SMACs and FULs. On September 28, 2001, Roxane divested certain NDCs at issue in this Action to Elan Pharma International Ltd. ("Elan"). (Dkt. 6202, at ¶ 253). After the divestment, Elan owned all of the NDAs associated with these NDCs and assumed all liabilities and obligations arising from the manufacture, sale, and marketing of these products. (*Id*. at ¶ 254). It appears that the DOJ seeks some $69 million in Medicaid damages for Roxane's drugs, and Medicare damages for Roxane's ipratropium of some $234.3 million (leaving aside the challenged NovaPlus issue).

Some of the most striking differences in proof which will either cause jury confusion, prolong the trial, or both, can be summarized as follows:

- The DOJ has no evidence that Dey actively "marketed the spread" for ipratropium or for any drug after 1997. However, the DOJ points to evidence of marketing the spread by Roxane after 1997, including for drugs at issue which were not sold until after 1999.
- Dey reported a declining WAC for its products while Roxane did not report WACs after December, 1997.
- Dey's expert will show that Dey's reported WAC was a transactional price with some transactions paid above WAC.
- In 1999, Dey began sending price notification letters to State Medicaid Agencies and DMERCs which explained its definition of AWP and WAC.
- Dey did not raise its AWPs for the Subject Drugs while the DOJ claims Roxane did.
- For Medicare, the choices made by the DMERCs in choosing which products to put in an array will lead to different and confusing arguments. For example, at some points in time Dey's products should not have been included in an array under applicable rules because the product was listed as preservative free. The categorization of products in Medicare arrays results in different causation arguments for Dey and Roxane.
- Dey has different experts than Roxane, and the experts performed different analyses. For example, Dey analyzed all available state claims data for its drugs while Roxane did not.
- The DOJ's damages expert used 14 states claims data for Dey but 16 for Roxane, thus requiring different expert presentations on extrapolation and different presentations on claims data or lack thereof.
- Dey and Roxane will have different fact witnesses.

- Dey has not participated in the depositions of Roxane's fact witnesses or Roxane-specific experts, and Roxane has not participated in the depositions of Dey's fact witnesses or Dey-specific experts, and therefore a joint trial will require each defendant to prepare for a large amount of new information unnecessary to their respective cases.
- SMAC and FUL evidence will be different for each drug and prolong the trial.
- Different company-specific evidence will be needed to prove the unjust enrichment claim against Dey or Roxane should the claim survive summary judgment.
- The knowledge by CMS and the state Medicaid agencies vary drug by drug.

In sum, asking a jury to try to keep all of this straight in a prolonged trial would be unfair to the jury, the Court, and the parties. Instead, two separate trials will be shorter and cleaner, with less tendency to error. Dey's trial will center on its three inhalation drugs, its unique pricing patterns, its own story and the states' and CMS' and their agent DMERCs' reimbursement policies and knowledge concerning these drugs and their dispensing costs. Presumably, Roxane's trial will center on its nine drugs, only one of which is an inhalation drug, and its story as a long-time generic competitor with a substantial portfolio. In each case, the Government knowledge issue is substantially different since Dey will focus on the mid-1990's while Roxane will presumably focus on the early 2000's.

ARGUMENT

I. CONSOLIDATION OF THE DEY AND ROXANE ACTIONS WOULD RESULT IN JURY CONFUSION AS WELL AS A PROLONGED TRIAL

Consolidation is inappropriate where individual issues predominate; where consolidation would make trial confusing, unmanageable or inequitable; or where "the desire for judicial efficiency would not be served [by consolidation] since the unique details of each case would still need to be presented to the jury." *In re. Consol. Parlodel Litig.*, 182 F.R.D. 441, 444-46 (D.N.J. 1998) (denying consolidation). Here, a joint trial will serve to add unnecessary length as well as juror confusion to what the DOJ admits is an already complicated trial. (U.S. Memo at 2).

A. This Court and Others Have Noted the Likelihood of Juror Confusion in AWP Cases

During the Track One trial, which involved four defendants, fourteen drugs and only Medicare, this Court noted several times that consolidation is confusing, and made clear that any jury trials should be of individual defendants:

> Let me just say to plaintiffs, I know you want to put three defendants up because you want to move this case. It is too confusing. It was so confusing to me doing Track One with all the different drugs…. It's just too confusing to a jury. We're going to do one drug.

MDL Transcript 8/27/2007, at 11:3-11:8, attached as Ex. A; *see also id*. at 28:17-29:3 (in considering the possibility of a jury trial of three defendants, the Court stated "I'm not sure I can try them all at once, simply because *I think it's confusing for a jury to keep track of all of them*") (emphasis added). This Court also remarked that the issues concerning individual defendants in the Track One trial were "quite significant" and created a huge amount of work for the Court. *See* MDL Transcript 12/8/06, at 75-76, attached as Ex. B.

In the Wisconsin pricing litigation, Judge Richard G. Niess of the Wisconsin Circuit Court decided, after his experience overseeing the first trial against only one defendant, that trying multiple defendants at the same time would be too confusing for a jury:

> I'm, frankly, not inclined to try more than one defendant at a time. I thought that while the presentations were excellent on both sides in the . . . case, Counsel was efficient… I think we face a real problem with jury confusion by combining [defendants]. I don't think there are any shortcuts here.

State of Wisconsin v. Abbott Labs., et al., No. 04-CV-1709, 3/10/2009 Motion Hearing, at 13, attached as Ex. C. The risk of confusion also has the potential to complicate the Court's work. In a later decision, after reviewing a clearly erroneous verdict setting the number of false statements, Judge Niess again commented on his decision to sever the trials in Wisconsin:

> This task has substantially validated this court's decision to sever the trials against each individual defendant in this mass litigation. Had all cases been tried together, this court would have been faced with the virtually unendurable burden of combing a massive transcript from months of trial to glean the credible evidence pertinent to calculating each of over 30 defendants' misrepresentations under the Medicaid fraud statute- a burden entirely caused by just one fallacious, overreaching jury argument. Needless to say, this jury argument will not be repeated in any future trial, absent further directive to the contrary from the appellate courts.

9/30/09 Decision and Order on Remaining Forfeitures Issues, at Fn1, attached as Ex. D. With fewer moving pieces, trials can be more streamlined, efficient, and less prone to error.

B. Here the Differences Between Dey and Roxane Make Consolidation Ripe for Confusion

The dissimilar facts that will need to be heard by a jury far exceed any "common" facts cited by the DOJ.[1] The False Claims Act requires proof of individual action. Therefore, trials of Dey and Roxane will require a jury to examine the facts on a company, drug, NDC, and yearly level. This approach has been previously articulated by this Court, which described its role as a fact-finder in the Track 1 trial as follows: "when it came down to it, for me, it was not only company by company, but drug by drug, NDC by NDC, and even – and year by year."). MDL Transcript 7/3/07, at 22:15-21, attached as Ex. E. Consolidation will result in numerous areas of confusion.

1. Confusion Resulting from Different Types of Drugs and Programs. It would be unmanageable for one jury to examine the 26 Dey NDCs and 35 Roxane NDCs, a total of 12 drug products, across almost fifty states and the Medicare and Medicaid programs. Rather than

[1] Upon review, many of the alleged "central" common facts set forth by the DOJ boil down to further argument of their factually unsupported negligence "joint" theory of damages and their comparison of Dey and Roxane's initial disclosures, which is meaningless in terms of the witnesses actually to be called at trial. The fact that Dey and Roxane coordinated depositions with Abbott and the DOJ is because of the MDL procedures, and not an argument for consolidation. Furthermore, Dey did not attend depositions of Roxane's specific witnesses or experts, and Roxane did not attend depositions of Dey's specific witnesses or experts.

presenting evidence on only Dey's three inhalation drugs, which in and of itself is challenging, a single jury would be presented evidence on Dey's inhalation drugs and then all of the Roxane immune suppressants and painkillers as well as its single inhalation drug. On a fundamental level, the differences between the drugs at issue in the two cases alone will cause mass confusion which is not curable by jury instructions. What jury instruction could be given when the problem is the mass of factual information which will be presented to a jury over the course of many months? *See, e.g., Walker v. H. Councill Trenholm State Tech. Coll.*, No. 2:06 cv 49-ID, 2007 WL 1140423, at *4 (M.D. Ala. Apr. 17, 2007) (court disagrees that preventive measures, such as cautionary jury instructions, can sufficiently alleviate the potential of jury confusion or prejudice, and denies consolidation).

Dey's drugs are all inhalation drugs used to treat respiratory diseases. With the exception of ipratropium, Roxane's drugs are oral tablets used for pain maintenance, autoimmune disease, arthritis, and congestive heart failure. As stated by another court in this Circuit, similar legal issues with different facts cause impermissible confusion:

> This is a jury action where the jury would be confused and overwhelmed to consider the evidence of each case and where the consolidation would not effect any appreciable saving of time or expenses since the defendants' alleged contribution to plaintiffs' damages involve proving separate set of facts. Therefore, the possible prejudice to defendants due to the likelihood of confusion in the minds of the jurors because of the similarity of issues alleged in the complaints and the possibility of different facts in each case outweigh the benefits of any possible convenience or economy to be obtained from consolidation.

Arroyo v. Chardon, 90 F.R.D. 603, 606 (D.P.R. 1981) (internal citations omitted). The fact that there is an overlapping drug in the Dey Action and the Roxane Action only adds to the potential confusion. A jury would be forced to hear evidence of alleged "marketing the spread," damages, including the issue of NovaPlus, and other company-specific evidence relating to ipratropium,

while attempting to compartmentalize the evidence as to Dey and Roxane.

2. Confusion Resulting from Different Time Frames At Issue. As discussed in more detail on page 3, the different time frames at issue in the Dey Action and the Roxane issue will cause unnecessary juror confusion.

3. Confusion Resulting from Different Marketing/Scienter Evidence. The marketing, sales, and pricing evidence relating to Roxane's drugs, even Roxane's ipratropium, has no bearing on the pricing, sales, and marketing of Dey's drugs. Roxane's scienter is separate from Dey's scienter. However, by presenting evidence in a consolidated trial, the amount of evidence the jury will be required to process dramatically increases at the same time that the jury will be asked to maintain distinctions between the evidence as it relates to Dey or Roxane. This type of situation is specifically one that has been held to hold a risk of confusion that precludes consolidation. For example, in *Parlodel*, the court found consolidation inappropriate because "evidence of [defendant's] liability for its marketing practices will be specific to each Plaintiff … ," thus each case would require presentation of individual evidence as to what representations defendant had made to each Plaintiff, which would reduce any efficiency gained by consolidation and "compress critical evidence of specific causation and marketing to a level which would deprive [defendant] of a fair opportunity to defend itself." 182 F.R.D. at 446-47.

Courts have recognized the very real risk that a jury which is overburdened by presentation of evidence in a consolidated trial may find itself unable to fulfill its duties and instead simply "throw[] up its hands in the face of a torrent of evidence." *Malcolm v. Nat'l Gypsum Co*., 995 F.2d 346, 352 (2d Cir. 1993). In *Malcolm*, the Second Circuit remanded for a new trial because the jury apportioned liability equally to multiple defendants in an asbestos liability case, despite evidence which was "vague, minimal and heavily circumstantial" as to one

defendant, showing that the jury was unable to maintain distinctions between the individual cases and impermissibly counted evidence about individual defendants against all defendants. *Id.*

The U.S. Memo itself provides evidence of the risks of confusion that will result from consolidation. Throughout the memo, the DOJ makes general statements about the Dey and Roxane defendants without making any distinctions among the companies, including references to "defendants' price reporting conduct" and "defendants' reported AWPs." The DOJ acts as if Dey and Roxane are essentially the same, when the evidence is clear they are not. It is the DOJ's burden to prove its case against each defendant individually under the False Claims Act. It has not alleged any conspiracy claim under 31 U.S.C. § 3729(a)(3). The mere fact a former employee of Dey went on to work at Roxane is not a reason for consolidation.[2] The fact that DOJ's Memo is filled with such generalities shows that it faces challenges in that regard and indeed may hope that a jury will be unable to maintain distinctions between the two cases.

4. Confusion Resulting from Different Defenses and Government Knowledge. Any common issues relating to government knowledge are overcome by the individual presentations relating to specific knowledge held by CMS and the Medicaid agencies regarding each drug at issue. There are various state MACs and FULs for certain of the drugs, the implementation of DOJ AWPs for some but not all the drugs, dramatically different evidence on dispensing costs for inhalation drugs versus oral tablets, and different evidence of government reimbursement policy and knowledge relating to each drug that will need to be addressed.

The diverse defenses that will be raised by each company will also cause confusion. The WAC price by Dey was a publicly reported transactional price which declined over time. Roxane did not report WAC. Dey also sent price notification letters to state Medicaid officials

[2] That former employee, Mark Pope, has run a wine-bar and online wine store for the last decade. *See* http://www.bountyhunterwine.com.

and DMERCs beginning in 1999 stating its definition of AWP and WAC. Roxane did not. Furthermore, the Dey Action and Roxane Action will require different causation arguments regarding the Medicare arrays.

C. The Length of a Consolidated Trial Will Lead to Juror Confusion and Exhaustion

The DOJ admits that these cases are already complicated. Asking a single jury to hear the evidence necessary to both actions, most of which will be non-duplicative, will add unnecessary length to what will already be a very lengthy trial, furthering jury confusion and the risk of error. As stated by the Second Circuit, "[t]he systemic urge to aggregate litigation must not be allowed to trump our dedication to individual justice, and we must take care that each individual-plaintiff's and defendant's-cause not be lost in the shadow of a towering mass litigation." *Malcolm*, 995 F.2d at 350 (internal citation omitted).

II. CONSOLIDATION OF THE DEY AND ROXANE ACTIONS IS INAPPROPRIATE BECAUSE IT WILL RESULT IN PREJUDICE

A. Concerns of Prejudice and a Fair Trial Outweigh Considerations of Convenience and Economy

In balancing the factors for and against consolidation, "considerations of convenience and economy must yield to a paramount concern for a fair and impartial trial." *In re. Consol. Parlodel Litig.*, 182 F.R.D. at 444 (citations and brackets omitted). "Consolidation is inappropriate … if it leads to [] unfair prejudice to a party." *Criswell v. City of O'Fallon, Missouri*, 2007 WL 2669114, No. 4:06 cv 01565-ERW (E.D. Mo. Sept. 6, 2007) (quoting *EEOC v. HBE Corp.*, 135 F.3d 543, 551 (8th Cir. 1998). In *Arroyo v. Chardon*, the Court denied a motion for consolidation notwithstanding plaintiffs' identical allegations against defendants, where plaintiffs' claims "must be proven by presenting evidence of specific acts in which defendants acted [wrongfully] in each particular case." 90 F.R.D at 605. The Court found that

because "each defendant's alleged contribution to plaintiffs' damage involves a separate set of facts[, consolidation] will result to the detriment of the jury's function to weigh and consider impartially the evidence presented in each particular case and it may result in prejudice to the parties' right to a fair day in court." *Id*. at 605-06. Here, the specific individual facts and legal arguments at issue in the Dey Action and the Roxane Action will lead to prejudice if consolidation were granted.

B. Consolidation Will Prejudice Dey and Roxane

1. Prejudice from Collapsing Time Frames with Alleged Marketing Evidence. Consolidation will prejudice Dey and Roxane because the DOJ will attempt to paint Dey and Roxane with evidence of the other company's alleged "marketing the spread." The risk of prejudice associated with presenting this type of evidence in a joint trial is one which courts have found to preclude consolidation. *See, e.g*., *Dashnaw*, 2006 WL 1742174 at *4 (denying consolidation to prevent possibility that plaintiff with inferior evidence would prejudicially "bootstrap[]" its claims to similar but superior evidence supporting another plaintiff).

The DOJ has stated that it "intends to prove that Dey and the Roxane Defendants trained their respective sales forces to market the spread . . and that they in fact marketed the spread." (U.S. Memo at 4-5). The presentation of evidence specific to Dey and Roxane in and of itself will prejudice the jury. However, the risk of prejudice is even higher because the specific allegations of "marketing the spread" the DOJ has made against Dey are limited to pre-1997 and are not specific to ipratropium. In its cross-motion for partial summary judgment, the DOJ admits that it does not have evidence that Dey actively marketed the spread after 1997:

> The record is replete with evidence that Dey sales representatives actively marketed the spread to pharmacy customers during the 1990's. In 1997, the company was served with state and federal subpoenas that initiated lengthy investigations leading to law suits, including the present one. Affirmative marketing of the spread by

Dey appears to have diminished.

(Dkt. 6303 at 11). Given this statement by the DOJ, it is fundamentally unfair for a jury to hear evidence as to any alleged "marketing the spread" by Roxane from 1997 onward. The risk of "bootstrapping" is heightened by the fact that all of the Roxane drugs but ipratropium were not sold until 1999. Even in the limited materials given to the Court by the United States during the October 20, 2009 hearing, the United States included Roxane e-mails from 1998, 1999, and 2000 purportedly documenting "marketing of the spread" by Roxane. (Exhibits M (ipratropium), O (ipratropium), and P (which appears to relate to an azathioprine AWP rise) to United States' Presentation Exhibits, Table of Contents annexed as Ex. F).

Furthermore, there is also a high likelihood of prejudice to Dey from evidence the DOJ will introduce regarding the AWPs of some of Roxane's drugs. It was Dey's practice to set its AWP at launch for the Subject Drugs and not to raise it thereafter. (Dkt. 6190 at ¶ 70). However, based on the presentation given by the DOJ to this Court on October 20, 2009, the DOJ will likely point to instances when Roxane increased its AWPs. (*See, e.g.*, Graph A5, Fauci Ex. 3, Dkt. 6207). The evidence and testimony given by both Roxane and the DOJ surrounding substantial increases in Roxane's AWPs may well spill over to prejudice the jury against Dey.

It is equally prejudicial to Roxane for a jury to hear evidence of alleged "marketing the spread" by Dey for albuterol sulfate and cromolyn for the time period 1992 to 1996, before the time period when Roxane is accused of marketing the spread. Given the inconsistent evidence relating to both companies, a jury should only be asked to consider whether the acts of a single company violated the False Claims Act.

2. Prejudice Resulting from the DOJ's Joint Impact Theory. Consolidation will allow the DOJ to unfairly present its evidence of its unfounded joint impact theory as it were a

given.[3] The DOJ asserts that consolidation is warranted because "Dey and Roxane each legally caused a single injury to the Medicare program based on the combined impact of their price reporting on Medicare's allowable amount." (U.S. Memo at 14). They make no such claim for Medicaid. Counsel for the DOJ explained the Medicare "combined impact theory" at the October 20, 2009 summary judgment hearing as follows:

> Dey has moved for summary judgment on a piece of the case which relates to our view that the combined impact of Dey and Roxane must be considered. In short, after the third quarter of 2001, we can change the AWPs of Dey down to a penny, and it doesn't change the outcome, the median calculation. We can change the AWPs of Roxane down to 1 cents, and it still doesn't change the median calculation. However, if we change the AWPs, if we lower the AWPs of both Dey products and Roxane products by 1 percent or more, it does affect the median. And I think it's helpful to see why this happens, and what I'm going to do is go to a replicate of the next quarter when things change. This array is virtually identical with one exception: Apotex has entered the market with a new product. We can see that their AWP for a package of 25s is fairly high. It's $4.48, which is higher than the Dey products and the Roxane products. Now, under Dey's theory of the case on which they seek summary judgment, because there is one more company that has entered the market with an inflated AWP, according to Dey, the United States cannot recover a penny because Dey's products in isolation do not affect the median; likewise, Roxane products in isolation do not affect the median; and, according to their view of the case, the United States' ability to prove damages and recover evaporates because one additional company has entered the market.

10/20/09 Hearing Transcript at 24:24-25:24. Essentially, the DOJ has moved to consolidate the Dey Action and the Roxane Action so that it may seek damages for those quarters and time periods when it itself admits that it cannot prove damages based on Dey or Roxane's actions alone. Apparently, the DOJ has no problem with Apotex entering the market with an AWP

[3] Because there are numerous arguments counseling against a consolidated trial of the Roxane Action and Dey Action, Dey does not intend to address in this opposition all of the legal deficiencies of the DOJ's combined impact theory of damages. Suffice it to say, Dey disagrees with the DOJ's untenable theory and they reserve their right to challenge its fallacies, should it be necessary to do so, at a later date.

almost a dollar higher than Dey's: the DOJ's damage expert effectively assumed that Apotex' AWP was reflective of Apotex actual acquisition cost plus 25% because it had not been sued.

In support of its theory, the DOJ relies upon a single sentence citing four cases and language concerning negligence law from the Restatement (Second) of Torts. (U.S. Memo at 16). First, the FCA is not a negligence statute. *United States v. Taber Extrusions, LP*, 341 F.3d 843, 845 (8th Cir. 2003) ("innocent mistakes and negligence are not offenses under the [FCA]"). None of the DOJ's cases are applicable to the situation presented here. *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, No. 96-11651-PBS (D. Mass. Aug. 22, 2003) is a causation case, in which this Court held that there was a question of fact as to whether Defendant's conduct was a substantial factor in causing the presentation of false Medicaid claims. *Id*. at *5. In that case, the Court looked to common-law tort causation concepts articulated by the First Circuit as requiring that there be (1) a causal relationship between the conduct and the outcome (the substantial factor test) and (2) forseeability that the law will impose liability on the Defendant. *Id*. at *4. *Shyface v. Secretary of Health and Human Services*, 165 F.3d 1344 (Fed. Cir. 1999) involves the determination of a cause of death for purposes of the Vaccine Act, *Comdyne I, Inc. v. Corbin*, 908 F.2d 1142 (3rd Cir. 1990) involves the determination of causation of damages resulting from defamatory statements; and *Schipani v. McLeod*, 541 F.3d 158 (2d Cir. 2008) involves a three-car accident. The Restatement (Second) provisions cited in the cases and by the DOJ involves the issue of whether a negligent actor's conduct is a legal cause of harm. Even accepting that the borrowing of common law tort concepts in the context of causation into a False Claims Act case is proper[4], the DOJ's theory

[4] Not all judges have agreed that common law torts principles should be borrowed in False Claims Act cases. "[T]he False Claims Act is a punitive statute, and civil punitive statutes, like criminal statutes, are to be construed strictly. The Act is punitive in two respects. The availability of treble damages, even though it has 'a compensatory side, also has a punitive character.' In addition, § 3729(a)(7) of the Act provides for a penalty of $ 5,000 to $ 10,000

ignores both the prior rulings of this Court and the First Circuit's "foreseeability" test in arguing for its combined damages scenarios.

This Court has already firmly rejected the DOJ's theory in Track 1, in which it held: "[g]iven that there are no claims or evidence of conspiracy or joint enterprise, the pertinent legal question is whether [a defendant] can be said to have individually caused the plaintiffs' injuries." *In re Pharm Indus. Avg. Wholesale Price Litig*., 491 F. Supp. 2d 20, 99 (D. Mass. 2007) (emphasis added). The DOJ has not brought suit under 31 U.S.C. § 3729(a)(3), which holds liable any person who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)" and there are no other allegations of conspiracy or joint action here. Just as in Track 1, there is no evidence here to support the theory that the DOJ now sets forth.

The fact that the DOJ claims there are two fraudulent actors here does not distinguish this prior holding. The DOJ ignores the second requirement of the causation test it relies upon: forseeability. Dey can only be held responsible for its own actions because it was not foreseeable to Dey that the DOJ would claim that anyone, let alone Roxane, was a "fraudulent actor" or that the DOJ would allege wrongful conduct on the part of Roxane. There are no allegations or evidence of conspiracy, collusion, or joint effort between Dey and Roxane. The DOJ has dismissed its common law fraud claims against Dey with prejudice. The DOJ has presented no evidence that Dey knew how the four DMERCs created Medicare pricing arrays, how the DMERCs chose which products to put in the arrays, or whether Dey or Roxane's products were ever included in a particular array, let alone in an array together. The DOJ has presented no evidence that Dey would have had any knowledge that any competitor's prices were alleged to be inflated, and there is no legal basis or factual evidence to show that Dey had

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regardless of actual damages. Accordingly, I would refrain from "borrowing traditional principles of tort law to analyze causation for damages under the FCA." *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 734 (10th Cir. 2006) (Hartz J., concurring).

information regarding the pricing or pricing decisions of Roxane.

The fact that the DOJ has chosen to sue two out of several manufacturers of ipratropium does not make Dey responsible for Roxane's conduct. There are other manufacturers in the arrays, and DOJ itself admits that another manufacturer, entered the market with an AWP "which is higher than the Dey products and the Roxane products." (10/20/09 Tr. at 25:12-15). Yet, despite this higher AWP, the DOJ has not sued the other manufacturer. Under the DOJ's theory, Dey was to foresee that Roxane was engaged in fraudulent conduct while Apotex, with a higher AWP, was not. Litigation decisions cannot be the basis of damage awards, especially when billions of dollars are at stake under a punitive statute with treble damages.

Were the Court to consolidate, Dey and Roxane will be prejudiced by the mere fact that they would be tried together. A joint trial will lead to the potential of impermissible inferences regarding the conduct of Dey and Roxane. Through the presentation of alleged "marketing the spread" as well as the DOJ's attempts to improperly link Dey and Roxane, the DOJ will attempt to portray Dey and Roxane as conspirators rather than competitors, yet nowhere in these litigations has that ever been alleged. It is likely that a jury could infer from the fact that the companies were tried together that they in fact had been working together or had conspired, improperly giving credence to the DOJ's joint impact theory and so prejudicing Dey and Roxane. The Dey Action needs to be tried on facts, not improper or subliminal inferences.

3. Prejudice because of Dey and Roxane's Different Price Reporting on WACs. One of Dey's defenses is that it has reported a declining WAC for all of the subject drugs throughout the time period at issue. This declining WAC was published in the pricing compendia alongside the AWP for Dey's drugs. Dey's WAC closely tracks the prices which the DOJ now claims Dey should have been reporting as its AWP. Therefore, Dey anticipates that at

trial, it will present substantial evidence relating to WAC. On the other hand, Roxane stopped reporting WACs for its drugs in December, 1997. (Dkt. 6202, at ¶ 113). Were the Court to consolidate, the jury would have to listen to Dey's evidence on its reported WAC with evidence of sales made at or above WAC while at the same time the jury would have to assimilate Roxane's different rationale for not reporting WAC. It is not too much to expect the DOJ will argue that Roxane's decision not to report a WAC renders Dey's reporting inconsequential, an argument and inference highly prejudicial to Dey which if tried alone would not face such an argument.

4. Prejudice from the NovaPlus Issue. According to the DOJ's arguable theory, when NovaPlus is categorized as a brand and the DOJ's expert substitutes alternative AWPs into the arrays, "the NovaPlus prices are determinative of the allowed amount calculation and thus become the sole cause of the resulting loss to the Medicare program- eliminating any causal impact of Dey's false prices." (U.S. Memo at 17). Roxane has moved for summary judgment on the NovaPlus issue but if that motion is not granted, and NovaPlus becomes part of a consolidated trial, Dey will have every incentive to agree with the DOJ position since it would eliminate all Medicare damages for Dey after NovaPlus enters the market.

5. Prejudice to Dey if the Court Allows Evidence Relating to Roxane's Affiliated Companies. The DOJ has also sued Roxane's sister and parent companies, and Roxane has filed a motion for summary judgment relating to these corporations. If that motion is not granted, according to the DOJ, "Ipratropium Bromide is the generic version of Atrovent, a branded drug marketed by Roxane's sister company (BIPI)." (U.S. Memo at 5). The trial will then inject the issues of the differences between branded drugs, first to market generics, and other generics. Dey should not have to be drawn into the middle of that as well as a piercing the

corporate veil argument over Roxane's related companies, which would have no bearing on Dey.

CONCLUSION

Far from shortening the trial, consolidation will substantially prolong any trial, injecting numerous issues, drugs, and testimony unrelated to Dey. Even the knowledge of CMS or state agencies will not be common, particularly since so much for Dey relates to time periods before Roxane drugs are at issue. Such a trial would dramatically increase the chance of error as an overwhelmed jury attempts to parse through the monumental amount of information and correctly apply the law to that evidence. As Judge Neiss said, "I don't thing there are any shortcuts here", mirroring this Court's own comments that combined trials would be confusing to a jury. For the foregoing reasons, this Court should deny the United States' Motion to Consolidate Cases for Trial in all respects and set the Dey Action and the Roxane Action for separate trials.

Dated: November 2, 2009

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on November 2, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid